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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/773,785	02/06/2004	Eric Finzi	6863-67727	7913

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EXAMINER	
FORD, VANESSA L	

ART UNIT	PAPER NUMBER
1645	

MAIL DATE	DELIVERY MODE
07/22/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/773,785	FINZI, ERIC	
	Examiner	Art Unit	
	VANESSA L. FORD	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 June 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-8,13-17,19,20,23 and 24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5-8,13-17,19,20,23 and 24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 February 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This action is responsive to Applicant After-Final Response filed June 12, 2009. Claims 2-4, 9-12,18 and 21-22 have been canceled. Claims 1, 5-8, 13-17, 19-20 and 23-24 are under examination. The finality of the last Office action mailed April 15, 2009 is withdrawn.

A *new Non-Final* is set forth below.

Rejections Withdrawn

2. In view of Applicant's amendment and response the following rejections are withdrawn:

(a) rejection of claims 1, 4-8, 12-15 and 23-24 under 35 U.S.C. 103(a), pages 2-11, paragraph 3 of the Final Office action.

(b) rejection of claims 16-21 under 35 U.S.C. 103(a), pages 11-14, paragraph 4 of the Final Office action.

New Ground of Rejection

Scope of Enablement

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1, 5-8, 13-17, 19-20 and 23-24 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of

treating major depression or dysthymia in a subject, the method comprising selecting a subject diagnosed with major depression or dysthymia using specific clinical criteria for major depression or dysthymia the subject also has frown/glabellar lines and administering to a subject 30 to 50 unit equivalents of botulinum toxin to a corrugator or procerus muscle and wherein the subject is treated with a therapeutically effective amount of a serotonin specific reuptake inhibitors (SSRIs), does not reasonably provide enablement for a method of treating major depression or dysthymia in a subject, the method comprising selecting a subject diagnosed with a disorder consisting of major depression or dysthymia (only) using specific clinical criteria for major depression or dysthymia and administering to the subject 30 to 50 unit equivalents of botulinum toxin to a corrugator or procerus muscle and wherein the subject is treated with a therapeutically effective amount of a serotonin specific reuptake inhibitors (SSRIs). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The specification teach administration of botulinum toxin to a facial muscle, such as the fronalis, procerus, the corrugator supercilii, orbicularis oculi or depressor anguli oris (page 4). The specification discloses that the population of patients used in the claimed method have major depression or dysthymia as well as have frown/glabellar lines and a history of being treated with SSRIs (see pages 17-18, Examples 1-4).

The claims encompass treating a population of patients that have major depression and dysthymia *only*. Based on the examples disclosed in the specification, the population of patients being treated have frown/glabellar lines as well have major depression or dysthymia. The instant specification has failed to enable the claimed method. The prior art recognizes that acute anxiety and depression may be induced by loss of muscle sensation and muscle control after administration of botulinum toxin. See Brenner *(Southern Medical Journal, Vol. 92, No. 7, page 738).* The cited prior art teaches that administration of botulinum toxin may cause depression or acute anxiety. The prior art teaches that administration of botulinum toxin may have the opposite effect on patients than that intended by the claimed invention.

Factors to be considered in determining whether undue experimentation is required, are set forth in In re Wands 8 USPQ2d 1400. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art and (8) the breadth of the claims.

Applying the factors above to the facts of record, it is determined that:: 1) the art teaches that protein chemistry is highly experimental, 2) no declaration under 37 C.F.R. 1.132 or other relevant evidence has been made of record establishing the amount of experimentation necessary, 3), there is no teaching in the specification of a population of patients that consist of major

depression or dysthymia only, 4) the state of the art recognizes that botulinum toxin administration may cause depression and acute anxiety (which is contradictory to the claimed invention) and 5) the relative skill of those in the art is commonly recognized as quite high (post-doctoral level).

The instant specification does not enable the invention as claimed. However, as indicated above, the instant specification does enable a method of treating depression the method comprising selecting a subject diagnosed with major depression or dysthymia using specific clinical criteria for major depression or dysthymia and the subject also has frown/glabellar lines and administering to a subject 30 to 50 unit equivalents of botulinum toxin to a corrugator or procerus muscle and wherein the subject is treated with a therapeutically effective amount of a serotonin specific reuptake inhibitors (SSRIs). However, the cited prior art has taught that administration of botulinum toxin causes loss of sensation and muscle control may cause acute anxiety and depression in some patients which contradictory to the claimed invention.

In view of all of the above, the invention as claimed is not enabled.

Status of Claims

4. No claims allowed.

Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to VANESSA L. FORD whose telephone number is (571)272-0857. The examiner can normally be reached on 9 am- 6 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert Mondesi can be reached on (571) 272-0756. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Vanessa L. Ford/
Examiner, Art Unit 1645
July 20, 2009